

Remarks

In the final office action, claims 11-18 and 25-27 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 11-18 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled and as not complying with the written description requirement. Claims 19-24 and new claims 25-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,637,302 to Bombardelli et al. ("Bombardelli et al.").

In this Amendment, Claims 11, 13, 19, and 25-27 have been amended. No new matter has been added. It is believed that that no subsequent search on the Examiner's part is necessitated by virtue of this Amendment. Claims 11-27 are pending.

A. SUMMARY OF INTERVIEW

Applicant thanks the Examiner for granting a telephonic interview on October 31, 2003. During that interview, which took place between Applicants' attorney, Thomas P. Canty (Reg. No. 44,586) and Examiner Qazi, the rejections to claims 19-25 under 35 U.S.C. §103(a) were discussed in view of Bombardelli et al. Mr. Canty presented the argument that Bombardelli et al. does not teach or suggest the feature of ultrafiltration, as that feature is recited in claim 19. The rejections to claims 1-18 under 35 U.S.C. § 112 were also discussed. No exhibits were shown or demonstrated. No agreement was reached.

B. REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 19-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over US Patent No. 5,637,302 to Bombardelli et al. ("Bombardelli et al.").

Bombardelli et al. -- discussed in the present application on page 2, lines 13-15; page 5, line 28; page 11, line 8; and Fig. 2 -- teaches a procedure for purifying a crude extract of Ginkgo biloba leaves by subjecting the crude extract to "a plurality of solvent extraction procedures" in a fluid-fluid dispersion. At least one of these solvent extraction procedures "employ an organic solvent comprising toluene and preferably n-butanol." Column 4, lines 1-4. The toluene/butanol mixture is used to remove alkyl phenols and other undesired inactive lipophilic substances. Column 4, lines 62-67. As already mentioned in the present application, these organic solvents are associated with a potential health hazard.

Applicant has amended claim 19, to include a "hydroketonic liquid extract" in addition to the "hydroalcoholic liquid extract." Support for this feature is found in the original application, for example, at page 5, lines 9-11; page 1, lines 20-24; page 10, lines 6-8; and claim 9.

As amended, claim 19 recites a method of preparation that includes the specific step of "ultrafiltration of the absorbed extract solution, hydroketonic liquid extract, or hydroalcoholic liquid extract through a filter with an average pore size ranging from 2000 to 10000 Daltons."

Applicants submit that Bombardelli et al. utterly fails to suggest the step of ultrafiltration, (a term having a specific and well-understood meaning that encompasses filtering at a scale between nanofiltration and microfiltration). Moreover, Bombardelli et al. does not teach or suggest ultrafiltration with a filter having particularly small pore sizes, as specified in claim 19. On the contrary, Bombardelli et al. teaches to remove unwanted substances from the raw extract using a chemical, instead of a physical step: namely, by introducing the raw extract to a toluene/butanol mixture. The relationship between the claimed ultrafiltration step and the various steps described in Bombardelli et al. are schematically illustrated in Fig. 1 of the present application, in which the Bombardelli et al. patent (USP 5,637,302) is listed in the box in the middle of the drawing.

Furthermore, the claimed ultrafiltration step using a filter with an average pore size ranging from 2000 to 10000 Daltons also leads to unexpected results as compared with prior art methods. As is described in detail in the present application:

The invention is based on the completely unexpected finding that extract components that impede the water solubility of dry extracts can evidently be removed or at least deactivated just by targeted ultrafiltration, while the composition of the desired constituent groups of the extract remains essentially unchanged. In the case of *Ginkgo biloba* dry extracts, ultrafiltration causes even those ginkgolides regarded as difficultly soluble to completely dissolve in water.

The combination of extract properties according to the invention, namely water-soluble, native, consisting exclusively of plant part constituents and in particular free of solubilization agents and/or galenic aids, can evidently be brought about solely via ultrafiltration treatment.

The fact that a purely technical step can yield a dry extract completely soluble in water is all the more astounding, since previous solubility improvements for dry extracts could only be achieved by adding galenic aids or solutizers.

The ultrafiltrate freed of organic solvents can also be used directly according to the invention, i.e., without subsequent drying, for further processing, e.g., in pharmaceuticals, cosmetics and/or dietetic foodstuffs.

Application, page 9, lines 5-24.

Moreover, the claimed method and the Bombardelli et al. method lead to different end products. For example, slightly polar components that are desirable for the final extract product cannot be effectively extracted using the chemical method described in Bombardelli et al., whereas those components typically pass through the filter in the ultrafiltration step and become part of the final extract produced according to the claimed method. On the other hand, high molecular weight compounds are extracted and form part of the end product extract produced according to Bombardelli et al., but those compounds are removed by the ultrafiltration step recited in the present invention.

The Examiner refers to column 3, lines 1-21 of Bombardelli et al. as suggesting a dry extract that is readily soluble. However, Bombardelli et al. does not refer to the water-solubility of the described dry extract, and Applicants respectfully submit that the experience of the prior art strongly suggests that dry extracts produced as described in the cited passage are indeed not readily water-soluble, i.e., that they leave behind insoluble residues when mixed with water.

The poor water solubility of known enriched Ginkgo biloba dry extracts is a problem that is well documented in the prior art. For example, the problem of the poor water solubility characteristics and some of the solutions for improving the water-solubility are discussed in patent documents EP0764659A1, DE4334600C2, EP0577143A2, and EP0275005, which were previously cited by the Applicant in a Form-1449, which are discussed on page 3, lines 4 through page 4, line 5 of the present application, and which are shown schematically in the lower left hand corner of Fig. 1. Each of these documents describes the use of chemical solubilization agents or galenic agents for improving water solubility. There has been no teaching in the prior art of using ultrafiltration to improve the water-solubility of Ginkgo biloba.

Accordingly, because the ultrafiltration step is present in each of claims 19-24 and 26-27, Applicant respectfully request withdrawal of the rejections to these claims under 35 U.S.C. §103(a).

Claim 25 was also rejected under 35 U.S.C. § 103(a). Claim 25 depends from claim 11 and recites the further feature that the extract does not include a galenic aid. Applicants submit that Bombardelli et al. does not teach or suggest a water-soluble dry extract of Ginkgo biloba as described in independent claim 11 and further lacking galenic acids.

Accordingly, withdrawal of the rejection to claim 25 under 35 U.S.C. § 103(a) is respectfully requested.

C. INDEFINITENESS REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 11-18 and 25-27 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, since the use of the term “including” in those claims was considered unclear.

Applicant has amended independent claim 11 to replace the phrase “not including a solubilization agent” with the phrase “wherein the extract lacks any solubilization agent.” In addition, claims 13, 26, and 27 were amended to replace “include” with “comprise”, and claim 25 has been amended to replace “not include” with “not have”.

Applicants respectfully submit that the language of claims 11-18 and 25-27 is clear and definite and that the scope of those claims is readily ascertainable.

Accordingly, withdrawal of the rejections to claims 11-18 and 25-27 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

D. REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 11-18 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled and as not complying with the written description requirement. The Examiner asserts that the feature recited in claim 11 “not including a solubilization agent” is new matter.

Applicant has amended independent claim 11 to recite a “a water-soluble, native dry extract consisting essentially of Ginkgo biloba plant part constituents, wherein the extract is produced by ultrafiltration using a filter having an average pore size ranging from 2000 to 10000 Daltons and wherein the extract lacks any solubilization agents.”

Support for the claimed features is found, for example, on page 4, line 24 to page 5, line 2, and page 7, lines 1-19. Applicant further submits that the invention of independent claim 1 is clearly described throughout the specification in detail and in Fig. 1, including how to make and use the extract. Withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

Moreover, Applicants submit that claim 11 is patentably distinct from the prior art, which use chemical procedures to improve the solubility of the extract. According to the present invention, the solubilization of the dry extract is achieved by physical means (i.e. ultrafiltration)

instead of chemical means. The known prior art describes dry extracts of Ginkgo biloba, which are either: (1) not water-soluble; or (2) which contain chemical or galenic solubilization agents so as to achieve solubility. In addition, the prior art dry extracts are not described as having been produced using ultrafiltration.

CONCLUSION

In view of the amendments made and arguments presented, Applicants respectfully submit that claims 11-27 are in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: 

William C. Gehris (Reg. No. 38,156)

Davidson, Davidson & Kappel, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940